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The Effects of Ocular and Lens Parameters on the Postlens Tear Thickness

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Purpose. To assess the effects of soft contact lens base curve radius (BCR), sex, ethnicity, central corneal curvatures, and vertical palpebral aperture size (PAS) on the postlens tear thickness (PLTT). **Methods.** The PLTT was measured using optical pachometry on 114 experienced lens wearers who were fitted with lathe-cut soft lenses (Alden 47, polymacon, 35.5% H₂O, −2.00 diopter, and 14.0 mm). Each subject was randomly allocated to one lens group receiving a BCR of 7.9, 8.3, or 8.7 mm. Pachometry measurements were taken at 30 min after lens insertion. Vertical PAS and keratometry readings were measured for 94 of the 114 subjects. **Results.** The mean (95% confidence interval) PLTT was 15.7 μ m (13.2–18.0 μ m), 12.8 μ m (10.9–14.7 μ m), and 12.1 μ m (10.2–14.0 μ m) for the 7.9-mm, 8.3-mm, and 8.7-mm BCR groups, respectively. The differences in PLTT among the three BCR groups was significant (analysis of variance F-test; $P=0.039$). Post hoc testing using the Tukey honestly significant difference statistic showed that only the two extreme BCR groups (7.9 mm and 8.7 mm) were significantly different. Sex had no effect on the PLTT; however, the PLTT was significantly thinner for the Asian compared with non-Asian eyes ($P=0.0001$). The Asian PLTT did not vary with different soft lens BCRs. The non-Asian PLTT was thicker with lenses of the steep BCR compared with the flat BCR. **Conclusion.** These results show that the base curve radius of a soft contact lens and several ocular characteristics can affect the thickness of the postlens tear film.

Key Words: Tear film—Soft contact lens—Ethnicity—Pachometry—Asians.

Efficient tear mixing under a soft contact lens decreases the contact time that debris and potentially harmful pathogens (e.g., cytotoxic strain of *Pseudomonas aeruginosa*) have with the corneal epithelium.^{1–3} It is possible that decreasing exposure to these unwanted substances during the presence of a soft lens minimizes mechanical irritation to the epithelial surface and reduces the ocular morbidity associated with soft lens extended wear. It has been suggested using a dispersive mixing model that tear mixing under a soft lens monotonically increases with the postlens tear

thickness (PLTT), and therefore, strategies involving lens design and materials to increase the PLTT may prove useful in improving tear exchange.⁴

We have shown that it is possible to make reliable in situ measurements of the PLTT.⁵ Because increasing the PLTT may be important to improving the tear mixing efficiency under soft lenses, it is important to understand what lens and ocular parameters may affect the thickness of the postlens tear film. One lens parameter is the base curve radius (BCR) because previous work using rigid lenses on a model eye shows that the PLTT is a function of BCR.⁵ Also, because eyelid anatomy and corneal curvature likely affect contact lens performance, it is reasonable to explore the roles of these two parameters on the PLTT. These observations raise some questions. Can changing the BCR alter the PLTT under a soft lens? Does lid anatomy or corneal curvatures affect the PLTT? Furthermore, the eyelid anatomy differs between Asians and non-Asians. For example, there is more obliqueness of the Asian palpebral aperture, and the orbital fat content extends farther inferiorly and superiorly in the upper and lower Asian eyelids, respectively, when compared with non-Asians.⁶ Are there also differences in the PLTT between Asians and non-Asians? To answer these questions, we assessed the effects of soft lens BCR, vertical palpebral aperture size (PAS), central corneal curvatures, and sex on the PLTT. We identified significant predictor variables for the PLTT and examined how their relative contributions varied for different ethnic groups.

MATERIALS AND METHODS

Soft Lens Material and Design

Custom-designed Food and Drug Administration group 1 hydrogel lenses of polymacon polymer with a water content of 38%, elastic modulus of 0.81 mPa, and refractive index of 1.435 were used (Alden 47; Alden Optical Laboratory, Inc., Alden, NY). All lenses were lathe cut to specifications of −2.00 diopters (D), 14.0-mm overall diameter, 12.5-mm optic zone diameter, 110- to ~120- μ m of center lens thickness, and a standard peripheral-curve design. Lenses were ordered in three different BCRs: 7.9, 8.3, and 8.7 mm.

Subjects

A total of 114 experienced soft lens wearers (75 women, mean age \pm SD, 22.5 \pm 3.9 years) were recruited from the University of California at Berkeley. We excluded from the study any potential subjects who were currently taking medications or had systemic conditions or seasonal allergies that could alter the quality or quantity of the tear film. All qualified participants were required to

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discontinue lens wear for at least 24 hr and to report to our laboratory a minimum of 2 hr after awakening.

The number of subjects ($n = 38$ in each of the three BCR groups) selected for the study was based on the sample size estimates obtained from the previous study that indicated the number needed to detect a difference of $3 \mu\text{m}$ in the PLTT.⁵ Informed consent was obtained after a full description of the study protocol. The research followed the tenets of the Declaration of Helsinki, and the research protocol was approved by the institutional review board (Committee for Protection of Human Subjects).

Instrumentation

A modified Haag-Streit optical pachometer, equipped with small light emitting diodes to improve patient fixation and alignment, was used to obtain the value of central PLTT. As previously reported, to obtain PLTT values, two pachometry measurements are needed: (1) baseline corneal thickness and (2) total thickness of the cornea, PLTT, and contact lens.⁵ For each pachometry measurement, 20 replicate readings were taken within a period of 2 to 3 min and then averaged. The validation of this technique and the optics applied for obtaining PLTT values have been described elsewhere.⁵ In the present study, the correction factors of 0.929 and 0.935 were applied to the baseline corneal thickness and total thickness measurements, respectively, to account for differences in refractive indices.

Procedure

Each subject was allocated randomly to one of three BCR groups based on a predetermined randomization scheme, from which the eye receiving pachometry measurements (i.e., the treatment eye) was also specified. The central keratometry and baseline corneal thickness were obtained only in the treatment eye, followed by lens insertion on both eyes. Having lenses in both eyes was necessary to minimize possible reflex tearing induced by unequal comfort levels between eyes. Ten minutes after lens insertion, the subjects were asked to rate the lens comfort based on a scale of 0 to 50 (0 = impossible to wear and 50 = very comfortable with no lens sensation), and then the lens fit was assessed. The measurements were terminated if the lens comfort for either eye was less than 35 or if the lens did not properly center on the treatment eye. Thereafter, vertical PAS of the treatment eye was measured using a millimeter ruler while subjects were relaxed and looking straight ahead.

Thirty minutes after lens insertion, the total thickness (T), combining the thickness of the cornea (B), contact lens (C), and PLTT, was measured. After the total thickness measurements, the lens was removed, and the center thickness of the lens was immediately measured using an electronic thickness gauge (Model ET-3, Rehder Development Company, Castro Valley, CA). The value of PLTT was obtained by the equation $\text{PLTT} = T - (B + C)$.

Statistical Analysis

The conservative sample size estimates to detect a $3\text{-}\mu\text{m}$ difference in the PLTT with a type I error of 5% and power of 80% was calculated using the largest variance of 43.55, reported in an earlier study.⁵ One-way analysis of variance (ANOVA) was first used to assess the difference in the mean PLTT among lens groups and in the ocular parameters between Asian and non-Asian subjects. Multiple linear regression models were used to evaluate the asso-

TABLE 1. The mean \pm SD of the measured ocular characteristics on 94 subjects^a

	Non-Asians	Asians	P-values
PAS (mm)	10.8 ± 1.3	9.6 ± 1.2	<0.0001
HK (D)	43.78 ± 1.48	43.13 ± 1.34	0.027
VK (D)	44.47 ± 1.55	44.16 ± 1.37	0.304
ΔK (D)	0.69 ± 0.60	1.03 ± 0.64	0.017

The vertical palpebral aperture size (PAS), horizontal and vertical keratometry readings (HK and VK, respectively), and central corneal toricity (ΔK) compared between non-Asian ($n = 41$) and Asian ($n = 53$) groups.

ciation between the PLTT and lens BCRs while adjusting for other potential confounding variables such as sex, corneal curvatures, corneal toricity, and vertical PAS. Models with and without an interaction term between PAS and corneal curvature were compared using the likelihood ratio test. The results with $P \leq 0.05$ were justified as significant for all tests.

RESULTS

The means (95% confidence interval [CI]) of the central PLTT were $15.7 \mu\text{m}$ ($13.2\text{--}18.0 \mu\text{m}$), $12.8 \mu\text{m}$ ($10.9\text{--}14.7 \mu\text{m}$), and $12.1 \mu\text{m}$ ($10.2\text{--}14.0 \mu\text{m}$) for the 7.9-, 8.3-, and 8.7-mm BCR groups, respectively. This might suggest that a greater thickness of the postlens tear film was associated with a steeper lens. To see whether the means were different among the three groups, ANOVA F-test was performed and yielded $P=0.039$, suggesting significant differences in the PLTT among the three BCR groups. Furthermore, to determine which two lens groups had a significant difference in PLTT, we performed post hoc testing with the Tukey statistic. The result showed that two extreme BCR groups (7.9 mm and 8.7 mm) were statistically different in the PLTT means ($P=0.018$).

In addition, information on sex, corneal curvatures, and PAS were available on a subset of subjects ($n = 94$). Subjects were further categorized into Asian and non-Asian groups to study whether there was racial disparity in PLTT between the two groups. The Asian group consisted of Chinese, Japanese, Korean, Taiwanese, and South Pacific Islanders, whereas the non-Asian group consisted of Hispanics and whites. Of the 94 subjects, there were 53 Asians (36 women) and 41 non-Asians (26 women). The mean (95% CI) age for Asians and non-Asians was 21 years (20–22 years) and 22 years (21–23 years), respectively.

Tables 1 and 2 show the measured ocular characteristics and the PLTT values for Asian and non-Asian subjects, respectively. The measured ocular characteristics included the central vertical (VK) and horizontal (HK) keratometry readings, corneal toricity ($\Delta K = |VK - HK|$), and vertical PAS. In Table 1, several ANOVA F-tests suggested that Asians, compared with non-Asians, had smaller vertical openings of the eyes ($P<0.0001$), flatter cornea in the horizontal meridians ($P=0.027$), and a greater amount of corneal astigmatism ($P=0.017$). In addition, the PLTT found in the Asian

TABLE 2. The mean \pm SD of the postlens tear thickness for base curve radius (BCR) of 7.9 mm and 8.7 mm compared between non-Asians ($n = 41$) and Asians ($n = 53$)

BCR	Non-Asians (μm)	Asians (μm)	P-values
7.9	20.3 ± 4.1	10.1 ± 2.4	<0.0001
8.7	17.3 ± 3.7	8.7 ± 2.9	<0.0001

TABLE 3. The results of the final model for the non-Asian postlens tear thickness on the scale of square-root function

Explanatory Variable	Regression Coefficient	SE	P-value
SBC	1.359	0.420	0.003
MBC	0.718	0.434	0.107
PAS	10.339	4.377	0.024
HK	2.287	1.067	0.039
HK \times PAS	-0.239	0.100	0.022

SBC, steep base curve radius of 7.9 mm; MBC, medium base curve radius of 8.3 mm; PAS, palpebral aperture size; HK, horizontal keratometry reading; HK \times PAS, interaction term of HK times PAS.

TABLE 4. The results of the final model for the Asian postlens tear thickness on the scale of square-root function

Explanatory Variable	Regression Coefficient	SE	P-value
PAS	0.246	0.140	0.084

PAS, palpebral aperture size.

eye was significantly thinner ($P < 0.0001$) than non-Asians, as shown in Table 2.

To carefully explore the individual contributions of the covariates as predictors, a series of regression analyses were used separately for the non-Asian and Asian subjects. Because of the strong correlation between VK and HK ($r = +0.9$) for all subjects, regression models did not include both variables to avoid problems caused by multi-collinearity. Tables 3 and 4 show the results of the final models for the non-Asian and Asian eyes, respectively. To better reach the normality assumptions, the PLTT values were all transformed in the scale of square root function ($\sqrt{\text{PLTT}}$).

By adjusting for PAS and HK, the mean $\sqrt{\text{PLTT}}$ of the steep lenses was approximately $0.7 \mu\text{m}$ ($P = 0.104$) and $1.4 \mu\text{m}$ ($P = 0.02$) thicker than those of the medium- and flat-BCR lenses, respectively. This model also suggested that variations in the BCR of a soft lens and in the subjects' ocular characteristics (e.g., HK and PAS) had significant roles in altering the non-Asian PLTT. In fact, the effect of PAS on the PLTT depended on the HK ($P = 0.005$). Models with and without the interaction term between PAS and HK were compared using the likelihood ratio test ($P = 0.0074$). To better understand the interaction between PAS and HK on the central PLTT, the model was further fitted with centralized PAS (i.e., centralized PAS = PAS - 10.8) and HK (i.e., centralized HK = HK - 43.78) variables. The results suggested that for a cornea with an average HK, the central PLTT decreased with increasing PAS when PAS was greater than 10.8 mm and increased with increasing PAS when PAS was smaller than 10.8 mm.

In contrast, changing the BCR of a soft contact lens did not affect the PLTT for Asians. The results of the final model demonstrated that PAS was the only variable that significantly contributed to the changes in the PLTT, although its effect on the $\sqrt{\text{PLTT}}$ was marginal ($P = 0.084$).

DISCUSSION

The results of this study show that changing the base curve radius of a soft contact lens alters the thickness of the postlens tear layer. This is in agreement with the clinical observations made on rigid lenses, which have shown that shortening the BCR in relation

to the corneal curvature increases the tear volume (e.g., steeper fitting pattern) beneath the lens. However, for the lenses used in this study, the change in PLTT was observed only on the non-Asian eyes, required a change in BCR of 0.8 mm or more, and was less than what would be predicted from the BCR-corneal curvature relationship. It is likely that the smaller than expected PLTT is because of the inherent flexibility of soft lenses.

We also found that the PLTT of the Asian eyes was significantly less by 9 to $\sim 10 \mu\text{m}$ compared with the non-Asian eye. This is most likely because of the smaller vertical palpebral aperture and the higher eyelid tension that result in more eyelid-lens interaction compared with the non-Asian eye with a large palpebral aperture.

Using the previous PLTT data obtained from etafilcon-A lenses (published and unpublished reports), we reanalyzed and stratified these results based on Asians and non-Asians and found no significant differences in the PLTT.⁵ However, when we excluded the influence of the upper eyelid by comparing only the non-Asian PLTT between polymacon and etafilcon-A lenses with a similar BCR, we found that polymacon lenses had thicker PLTT (e.g., $17 \mu\text{m}$) compared with the etafilcon-A lenses (e.g., $12 \mu\text{m}$). Of interest, the PLTT for the Asian eyes remains approximately $10 \mu\text{m}$, regardless of the lens types or BCRs.

One possible explanation for these PLTT differences between ethnic categories and lens types may be because of the difference in the lens modulus. For example, the elastic modulus of the polymacon lenses (e.g., 0.81 mPa) is almost three times higher than etafilcon-A lenses (e.g., 0.28 mPa). We suggest that polymacon lenses with the higher elastic modulus, greater center thickness, and lower water content are able to maintain a larger sagittal depth compared with the less elastic etafilcon-A lens. During blinking, soft lenses are compressed down toward the corneal surface. However, a soft lens with a higher elasticity (e.g., polymacon) is able to return back closer to its maximum sagittal depth during the inter-blink period compared with a lens with minimal elastic memory (e.g., etafilcon-A) that remains more conformed to the cornea. As the higher elastic lens recoils, it generates a net lower pressure in the postlens tear film drawing more tears than compared with a lower elastic lens.^{7,8} This may explain the PLTT difference between polymacon and etafilcon-A lenses when the confounding factor from the upper eyelid is not present. Furthermore, when a soft lens is able to maintain a vault on the corneal apex, the depth of the vault will depend on the position and the tension of the upper eyelid during the inter-blink period. This helps elucidate our observation that polymacon lenses were more influenced by the inter-subject differences in the eyelid anatomy than etafilcon-A lenses.

Of particular importance, the thinner PLTT and higher eyelid tension may help explain why the corneal epithelial barrier function of the Asian eyes responded differently to the closed-eye contact lens wear compared with the non-Asian eyes. The combination of a thin postlens tear film and a tight upper lid induces a high shear force applied to the ocular surface. This high shear force may, in part, explain why the Asian eye shows a substantially reduced corneal epithelial barrier function after overnight wear compared with the non-Asian eye.⁹

In summary, we have shown that both lens and ocular parameters can affect the thickness of the postlens tear film. This information may be useful in designing lenses specifically to improve tear mixing and to enhance the biocompatibility of a soft lens with the ocular surface.

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